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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,462	12/06/2001	Aillette Mulet Sierra	30797-717.201	4354
21971 7590 08/08/2007 WILSON SONSINI GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304-1050			EXAMINER HOLLERAN, ANNE L	
			ART UNIT	PAPER NUMBER
			1643	
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			08/08/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/003,462	<b>Applicant(s)</b> SIERRA ET AL.	
	<b>Examiner</b> Anne L. Holleran	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-7, and 12-18 is/are pending in the application.
- 4a) Of the above claim(s) 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicants' amendment filed 5/18/2007 is acknowledged.

Claims 8-11 and 19 were canceled. Claims 1, 2, 4-7, and 12-18 are pending.

Claims 14-18, drawn to non-elected inventions, are withdrawn from consideration.

Claims 1, 2, 4-7, 12 and 13 are examined on the merits.

2. The declaration of Belinda Sanchez Ramirez, filed under 37 C.F.R. 1.131, is acknowledged and has been considered.

#### ***Claim Rejections Withdrawn:***

#### ***Claim Rejections - 35 USC § 112***

3. The rejection of claims 8, 9, 10 and 11 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vaccines comprising an EGF molecule sufficiently characterized by physical or chemical structure, such as by SEQ ID NO, does not reasonably provide enablement for vaccines comprising EGF molecules identified solely as "EGF" is withdrawn in view of the amendment canceling the claims.

4. The rejection of claims 8, 9, 10 and 11 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment canceling the claims.

Art Unit: 1643

5. The rejection of claims 1, 2 and 4-13 under 35 U.S.C. 112, first paragraph, because the specification, for lack of enablement of vaccines comprising human TGF $\alpha$  linked to P64k either by chemical means or as a fusion protein is withdrawn in view of the amendment to the claims eliminating the term "vaccine" from the claims.

6. The rejection of claims 1, 2, and 4-13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

#### ***Double Patenting***

7. The provisional rejection of claims 1, 2 and 4-13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 10, 11, 12, 23, and 26 of copending Application No. 10/005,341 is withdrawn in view of the abandonment of this application.

#### ***Claim Rejections - 35 USC § 103***

8. The rejection of claims 1, 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over Hoeprich (of record) in view of Gonzalez (Gonzalez, S. et al, Scandinavian J. Immunol., 52: 113, 2000, August), in view of either Gonzalez-1997 (of record) or Gonzalez-1998(of record), and further in view of De Luca (De Luca, A. et al., Oncogene, 19(51): 5863-5871, 2000, Nov.) is withdrawn in view of the cancellation of claims 10 and 11.

Art Unit: 1643

***Claim Rejections Maintained:***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1643

9. Claims 1, 2, 7, and 12 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeprich (of record) in view of Gonzalez (Gonzalez, S. et al, Scandinavian J. Immunol., 52: 113, 2000, August) for the reasons of record.

Please note that in the previous Office action, the examiner failed to list claim 2 as rejected over the prior art. However, in the body of the rejection the limitation present in claim 2 (that TGF $\alpha$  is recombinantly synthesized) is mentioned: "Hoeprich teaches a conjugate of human TGF $\alpha$  and keyhole limpet hemocyanine, coupled using gluteraldehyde (see page 19087, 1<sup>st</sup> column). The TGF $\alpha$  was either chemically synthesized or recombinantly synthesized (see Figure 2 on page 19088 and page 19087, 1<sup>st</sup> column)". Therefore, the inclusion of claim 2 in this rejection is not considered new grounds.

Applicants' arguments have been carefully considered but fail to persuade. Applicants assert that Hoeprich fails to teach a vaccine composition as currently claimed wherein said carrier protein is P64k as required by the claims. Applicants point out the Gonzalez reference was published in August 2000 and thus is a 102(a) publication date, and that such a publication can be overcome by a 37 CFR 1.131 affidavit to antedate the reference.

The affidavit filed on 5/18/2007 under 37 CFR 1.131 has been considered but is ineffective to overcome the Gonzalez reference.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Gonzalez-2000 reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler*

Art Unit: 1643

*v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). Applicants assert that the affidavit by inventor Belinda Sanchez Ramirez demonstrates that the fusion proteins as claimed were conceived and reduced to practice prior to the August 2000 publication date of the Gonzalez reference. The affidavit refers to evidence provided by an Exhibit B, a page from a laboratory notebook that purportedly exemplifies the protocol used to generate P64-TGF $\alpha$  fusion protein as described in Examples 2 and 3 of the present application. However, the page from the laboratory notebook is in the Spanish language. Furthermore, what can be gleaned from Exhibit B is that some procedure was performed with a nucleic acid encoding for TGF $\alpha$  and with a vector referred to a pM92. However, one cannot discern from the notebook page that a fusion between TGF $\alpha$  and P64k was made or contemplated because the term P64k or *Ip dA* (the gene coding for P64k protein from *Neisseria meningitidis* (strain B385)) does not appear anywhere in Exhibit B.

10. Claims 1, 4-6, 12 and 13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeprich (of record) in view of Gonzalez (Gonzalez, S. et al, *Scandinavian J. Immunol.*, 52: 113, 2000, August) and further in view of Gonzalez-1997 (of record) for the reasons of record.

Applicants request withdrawal of this rejection for the reasons stated above that the Gonzalez reference published in August 2000 is not available as prior art because applicants conceived of and reduced to practice the invention before the publication date of Gonzalez. However, as discussed above the affidavit filed on 5/18/2007 under 37 CFR 1.131 is ineffective to overcome the Gonzalez reference.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Art Unit: 1643

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner  
August 1, 2007

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**

